IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9199

Bartle, J. January 29, 2014

Pat M. Hubbard ("Ms. Hubbard" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2010, claimant submitted a completed supplemental Green Form to the Trust signed by her attesting physician, Douglas S. Black, M.D., F.A.C.C. Based on an echocardiogram dated April 21, 2010,[3] Dr. Black attested in Part II of claimant's Green Form that Ms. Hubbard suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Because claimant's April 21, 2010 echocardiogram was performed after the end of the Screening Period, the Trust reviewed claimant's August 1, 2002 echocardiogram to establish her eligibility to receive Matrix Benefits.

Pondimin® and/or Redux™.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits[5] in the amount of $335,553.[6]

In the report of claimant's August 1, 2002 echocardiogram, the reviewing cardiologist, David Gonzalez, M.D., stated that claimant had severe mitral regurgitation, which he measured at 41%. Under the definition set forth in the Settlement Agreement, severe mitral regurgitation is present where the Regurgitant Jet Area in any apical view is greater than 40% of the Left Atrial Area. See id. §§ I.22 & IV.B.2.c.(2)(b). The Settlement Agreement requires the payment of reduced Matrix Benefits to a claimant who is diagnosed with mild mitral regurgitation[7] by an echocardiogram that was performed between

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4. Dr. Black also attested that claimant suffered from aortic sclerosis, a reduced ejection fraction in the range of 40% to 49%, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

6. Ms. Hubbard previously received Seventh Amendment Category One benefits in the amount of $245,497.70. If Ms. Hubbard's supplemental claim for Level III benefits is payable only on Matrix B-1, Ms. Hubbard will not receive any additional payment because the amount to which she would be entitled for her Matrix B-1, Level III claim is less than the amount she already received under the Seventh Amendment. See Settlement Agreement § IV.C.3.; Seventh Amendment § IX.A.2.

7. Under the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five

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the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a). As the Trust does not contest claimant's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In March, 2011, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.P., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for finding that claimant's August 1, 2002 echocardiogram demonstrated severe mitral regurgitation. Dr. Irani explained, "Only mild [mitral regurgitation] present. Significant overtracing of RJA to include noncolor encoded area."

Based on Dr. Irani's finding that claimant had only mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period, the Trust issued a post-audit determination that Ms. Hubbard was entitled only to Matrix B benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, Ms. Hubbard argued that her

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7. (...continued)
percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Id. § I.38.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit (continued...)

mitral valve surgery and additional medical conditions are the result of her Diet Drug use. In addition, claimant submitted numerous medical records and argued that she established a reasonable medical basis for finding that her August 1, 2002 echocardiogram demonstrated at least moderate mitral regurgitation because the auditing cardiologist is the only physician who has concluded that Ms. Hubbard had only mild mitral regurgitation. Finally, claimant submitted an August 11, 2011 letter from her attesting physician, Dr. Black, wherein he stated, in relevant part, that:

> ... I do not believe that Mrs. Hubbard had only mild mitral regurgitation. She had echocardiograms in my office on December 4, 2008, April 20, 2009, October 21, 2009, and April 21, 2010. She then had a [transesophageal echocardiogram] on July 13, 2011 at Wadley Regional Medical Center. Each of these studies reflected moderate to severe mitral valve regurgitation ....
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> It is my opinion that Mrs. Hubbard had moderate to severe mitral regurgitation with which she was symptomatic and ultimately improved with mitral valve repair ....

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Irani submitted a declaration wherein he again concluded that claimant's August 1, 2002 echocardiogram revealed only mild

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8. (...continued)
after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Hubbard's claim.

mitral regurgitation. Specifically, Dr. Irani stated, in relevant part, that:

> Based on my review, I confirm my finding at audit, that there is no reasonable medical basis to conclude that Claimant had moderate mitral regurgitation in between Diet Drug use and the close of the Screening Period. As I noted at audit, there is excessive overtracing of the regurgitant jet area ("RJA") on the 8/1/02 study, which includes non-color-encoded areas. At Contest, I digitized and made measurements on the 8/1/02 [echocardiogram] as follows: at 19:66:29, I measured a left atrial area of 25.53cm²; at 19:53 I measured an RJA of 3.06cm². The resultant LAA/RJA [sic] ratio of 13% is consistent with mild mitral regurgitation, and is representative of the level of mitral regurgitation present throughout the study. Accordingly, there is no reasonable medical basis to conclude that Claimant had moderate mitral regurgitation in between Diet Drug use and the close of the Screening Period.

The Trust then issued a final post-audit determination, again determining that Ms. Hubbard was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On November 29, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8711 (Nov. 29, 2011).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

documentation. Claimant then served a response upon the Special Master. The Trust did not submit a reply. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that she suffered from moderate or greater mitral regurgitation on an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant reasserts the arguments she made during contest. Claimant also argues that the auditing cardiologist improperly used the August 1, 2002 echocardiogram to reduce her claim to Matrix B-1 when the same echocardiogram was used to support her initial award of Seventh Amendment Category One Benefits.[10]

The Technical Advisor, Dr. Vigilante, reviewed claimant's August 1, 2002 echocardiogram and concluded that there was no reasonable medical basis for finding that it demonstrated moderate or greater mitral regurgitation. Specifically, Dr. Vigilante stated, in pertinent part:

> I reviewed the tape of the Claimant's Eligibility Echocardiogram. The Claimant's name and date of August 1, 2002 were documented.... This was a good quality study with the usual echocardiographic views obtained. Color flow evaluation was adequate with appropriate Nyquist limit of 63 cm per second at a depth of 15 cm in the parasternal long-axis view and 59 cm per second at a depth of 16 cm in the apical views. However, the supposed RJAs traced by the sonographer were inaccurate as they contain low velocity, non-mitral regurgitant flow.

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10. Claimant also argues the Trust improperly used a Screening Period end date of January 3, 2003. We disagree. The Screening Period ended on January 3, 2003 for an echocardiogram, like Ms. Hubbard's, that was obtained independent of the Trust's Screening Program and ended on July 3, 2003 for an echocardiogram obtained through the Trust's Screening Program.

> Evaluation of the mitral apparatus demonstrated that both mitral leaflets appeared normal with normal excursion. There was no evidence of mitral valve prolapse. There is no evidence of mitral annular calcification. Visually, mild mitral regurgitation was present. I digitized the cardiac cycles in the apical views in which the mitral regurgitant jet was best evaluated. I digitally traced and calculated the RJA and LAA in the apical four and two chamber views. I was able to accurately planimeter the RJA in the mid-portion of systole. The largest representative RJA in the apical four chamber view was 3.6 cm2. The LAA in the apical four chamber view was 19.9 cm2. Therefore, the largest representative RJA/LAA ratio in the apical four chamber view was 18% diagnostic of mild mitral regurgitation. The largest representative RJA in the apical two chamber view was 3.7 cm2. The LAA in the apical two chamber view was 20.9 cm2. Therefore, the largest representative RJA/LAA ratio in the apical two chamber view was 18% diagnostic of mild mitral regurgitation. There were no RJA/LAA ratios that reached 20% in either the apical four or two chamber views. The sonographer traced supposed RJAs of 7.57 cm2 and 8.14 cm2 in the apical two chamber view and 7.26 cm2 in the apical four chamber view. However, it is obvious that these determinations were inaccurate as they contained a significant amount of low velocity, non-mitral regurgitant flow. The sonographer's LAA determination of 20.6 cm2 is similar to my LAA determinations.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor Report establishes her entitlement to additional compensation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. The Settlement Agreement requires that a claim for benefits based on damage to the mitral valve be reduced to Matrix B-1 if the claimant had mild mitral

regurgitation diagnosed by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. Settlement Agreement § IV.B.2.d.(2)(a).[11]

As an initial matter, claimant does not adequately rebut the findings of the auditing cardiologist or the Technical Advisor. Dr. Irani reviewed claimant's August 1, 2001 echocardiogram and determined that claimant only had mild mitral regurgitation. Although claimant contested these findings, she did not identify any error in Dr. Irani's analysis. Dr. Vigilante also reviewed claimant's August 1, 2002 echocardiogram and concluded that only mild regurgitation was present. In addition, although claimant submitted a letter from her attesting physician, Dr. Black did not respond to the auditing cardiologist's determination as to claimant's August 1, 2002 echocardiogram. Rather, based only on claimant's later echocardiograms, Dr. Black opined that Ms. Hubbard had moderate to severe mitral regurgitation. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

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11. For this reason, we reject claimant's argument that the Trust could not rely on the August 1, 2002 echocardiogram to determine the presence of a reduction factor under the Settlement Agreement. While the August 1, 2002 echocardiogram may have resulted in the payment of Seventh Amendment Category One benefits, determinations and actions as to Category One class members "shall have no preclusive or precedential effect of any kind on the Trust in the administration of claims for ... Seventh Amendment Matrix Compensation Benefits." Seventh Amendment § IX.E.

Further, we are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case by case basis. For example, as we previously explained, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Irani determined that there was significant overtracing of claimant's regurgitant jet area in determining the level of claimant's mitral regurgitation. In addition, Dr. Vigilante determined that the "RJAs traced by the sonographer were inaccurate as they contain low velocity, non-mitral regurgitant flow." Further, Dr. Vigilante planimetered the largest representative RJA/LAA ratios and determined them to be 18% with no RJA/LAA ratio reaching 20% in any apical view. Such unacceptable practices cannot provide a reasonable medical basis

for the resulting diagnosis of moderate or greater mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that she had moderate or greater mitral regurgitation on an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Hubbard's claim for Matrix A-1 benefits.